



# Mallinckrodt Pharmaceuticals

Managing Complexity. Improving Lives.

J.P. Morgan Healthcare Conference  
January 7, 2019

# Forward-looking statements

Statements in this document that are not strictly historical, including statements regarding future clinical trials and commercial launches, future financial condition and operating results, economic, business, competitive and/or regulatory factors affecting Mallinckrodt's businesses and any other statements regarding events or developments that the company believes or anticipates will or may occur in the future, may be "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995, and involve a number of risks and uncertainties. There are a number of important factors that could cause actual events to differ materially from those suggested or indicated by such forward-looking statements and you should not place undue reliance on any such forward-looking statements.

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## These factors include risks and uncertainties related to, among other things:

- The proposed spin-off of the Specialty Generics/API (Specialty Generics) business inclusive of Mallinckrodt's AMITIZA® (lubiprostone) product, including the costs associated with the contemplated separation and spin-off, the expected benefits of the transaction, and the expected timeframe to complete such a transaction;
- General economic conditions and conditions affecting the industries in which Mallinckrodt operates;
- Mallinckrodt's ability to obtain regulatory approval to market its products or the timing of such approval process;
- The commercial success of Mallinckrodt's products;
- Mallinckrodt's ability to realize anticipated growth, synergies and cost savings from acquisitions;
- Conditions that could necessitate an evaluation of Mallinckrodt's goodwill and/or intangible assets for possible impairment;
- Changes in laws and regulations;
- Mallinckrodt's ability to successfully integrate acquisitions of operations, technology, products and businesses generally and to realize anticipated growth, synergies and cost savings;
- Mallinckrodt's and Mallinckrodt's licensors' ability to successfully develop or commercialize new products;
- Mallinckrodt's and Mallinckrodt's licensors' ability to protect intellectual property rights;
- Customer concentration;
- Mallinckrodt's reliance on certain individual products that are material to its financial performance;
- Cost containment efforts of customers, purchasing groups, third-party payers and governmental organizations;

# Forward-looking statements

- The reimbursement practices of a small number of public or private insurers;
- Pricing pressure on certain of Mallinckrodt's products due to legal changes or changes in insurers' reimbursement practices resulting from recent increased public scrutiny of healthcare and pharmaceutical costs;
- Limited clinical trial data for H.P. Acthar® Gel;
- Complex reporting and payment obligations under healthcare rebate programs;
- Mallinckrodt's ability to navigate price fluctuations;
- Future changes to U.S. and foreign tax laws;
- Mallinckrodt's ability to achieve expected benefits from restructuring activities;
- Complex manufacturing processes;
- Competition;
- Product liability losses and other litigation liability;
- Ongoing governmental investigations;
- Material health, safety and environmental liabilities;
- Retention of key personnel;
- Conducting business internationally;
- The effectiveness of information technology infrastructure; and
- Cybersecurity and data leakage risks.

These and other factors are identified and described in more detail in the "Risk Factors" section of Mallinckrodt's Annual Report on Form 10-K for the fiscal year ended December 29, 2017. The forward-looking statements made herein speak only as of the date hereof and Mallinckrodt does not assume any obligation to update or revise any forward-looking statement, whether as a result of new information, future events and developments or otherwise, except as required by law.



**Mallinckrodt**  
Pharmaceuticals

# Mark Trudeau

President and Chief Executive Officer



# Mallinckrodt Pharmaceuticals: Managing complexity. Improving lives.



**Strategic Vision:**  
Innovation-driven  
specialty pharmaceutical  
growth company focused  
on improving outcomes  
for underserved patients  
with severe and critical  
conditions

## Patients

- Neonates / infants
- Refractory and critically ill adults

## Therapeutic Focus

- Rare, severe, and critical diseases
- Critical care, autoimmune disorders, hepato-renal, and neurology

## Scientific Platforms

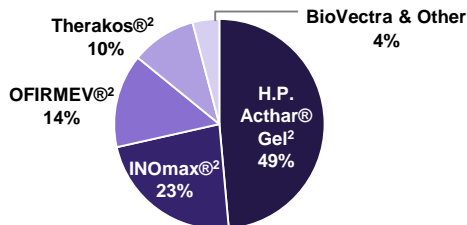
- Small/large molecules and biologics
- Regenerative cell- and tissue-based therapies
- Drug-device combinations and nitric oxide technologies

## Capabilities / Strengths

- Commercial execution in hospital, specialty care, NICU<sup>1</sup>, and patient services
- Development expertise in clinical data generation, label expansion, and drug-device development
- Manufacturing and supply chain
- Business development and licensing
- Cash flow generation and cost management

# Spin-off expected to create two focused, independent, well-capitalized publicly traded companies at scale

## Specialty Brands (To Be Named)



Product Mix<sup>1</sup>

LTM Sept. 2018  
Net Sales<sup>1</sup>

**\$2.3 billion**

CEO

**Mark Trudeau**

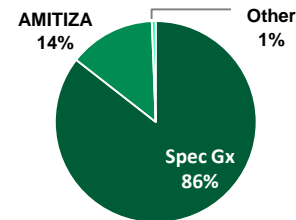
Strategic  
Focus

**Innovative branded drug development and commercialization**

Upcoming  
Milestones

- H.P. Acthar Gel: RA<sup>3</sup> trial and MS<sup>4</sup> registry readouts; complete enrollment in uveitis, lupus and ALS<sup>5</sup> trials
- P3 data: CPP1-X/sulindac, StrataGraft<sup>6</sup> and terlipressin
- P3 initiation: MNK-6105 and stansoporphin

## Specialty Generics (Assumes “Mallinckrodt” Name)



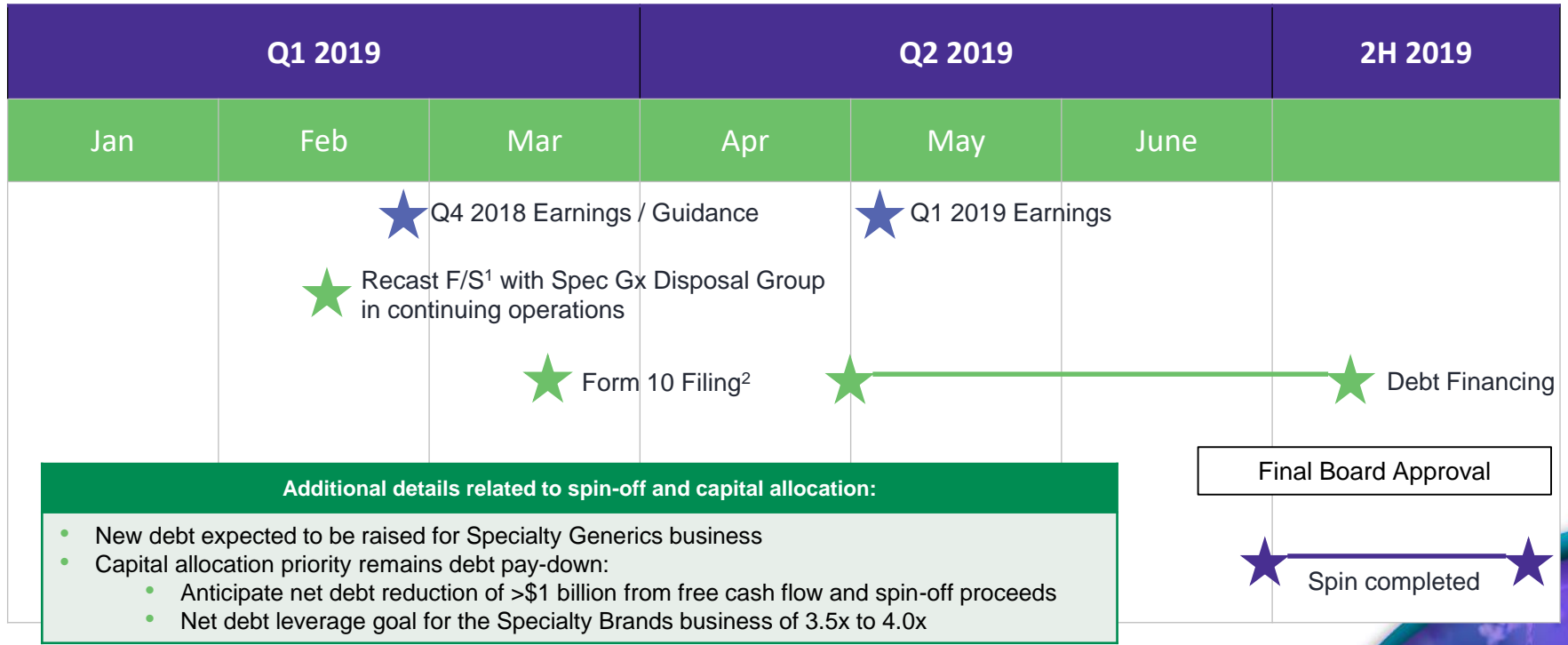
**\$0.9 billion**

**Matt Harbaugh**

**Complex ANDA<sup>7</sup> development and contract manufacturing**

**Launch of up to five new ANDA products**

# Spin-off expected to be completed in the second half of 2019 or sooner



<sup>1</sup> Recast financial statements will include FY18 (quarterly and nine-month results through Sept. 28, 2018) and FY17 (quarterly and annual);

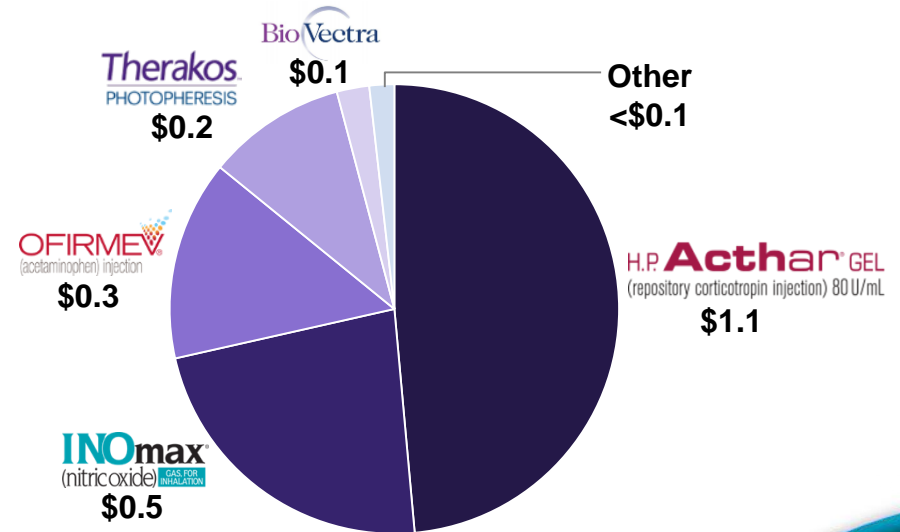
<sup>2</sup> Filing will include audited FY18, FY17, Transition Period 2016 (Represents the period from Oct. 1-Dec. 30, 2016) and FY16 financial information for the anticipated Specialty Generics spin-off business

# Diversified Specialty Brands business well positioned for growth

## Growth Drivers

- Long-term H.P. Acthar Gel Rx demand and access driven by clinical and HEOR data generation, new product presentation and potential label expansion
- Diversified in-line Hospital portfolio and multiple potential near-term launches
- Significant R&D investment both in absolute dollars and as a percentage of net sales
- Strong capabilities across commercial, R&D, manufacturing, and business development
- Disciplined cost management and capital allocation

## LTM Sept. 2018<sup>1</sup> Net Sales by Product (\$ in billions)



LTM Sept. 2018 Net Sales: \$2.3 billion



# Robust Specialty Brands late-stage pipeline aligned with therapeutic areas of focus

Product	PreClinical	Phase 1	Phase 2	Phase 3	Registration	Indication Under Study	Diseases/Therapeutic Areas
UVADEX® (methoxsalen) sterile solution (Therakos)						Chronic GVHD <sup>1</sup> (Japan)	Autoimmune
VTS-270 (2-hydroxypropyl- $\beta$ -cyclodextrin (HP $\beta$ CD mixture)				*		Niemann-Pick Disease Type C	Rare Disease & Neurology
CPP-1X-sulindac oral combination				*		Familial Adenomatous Polyposis	Rare Disease
TERLIPRESSIN vasopressin analog				*		HRS <sup>2</sup> Type-1	Hepato-Renal
STRATAGRAFT® regenerative skin tissue				*		Severe Burns, DPT <sup>3</sup>	Critical Care
XENON gas for inhalation						Post Cardiac Arrest	Critical Care
UVADEX (methoxsalen) sterile solution (Therakos)						Acute GVHD (U.S.)	Critical Care
STANNSOPORFIN heme oxygenase inhibitor						Neonatal Hyperbilirubinemia	Critical Care
MNK-6105 (OCR-002) (ornithine phenylacetate) intravenous						Hepatic Encephalopathy	Hepato-Renal
STRATAGRAFT regenerative skin tissue						Severe Burns, FT <sup>4</sup>	Critical Care
H.P. ACTHAR® GEL (repository corticotropin injection)						ALS <sup>5</sup>	Neurology
MNK-6106 (OCR-002) (ornithine phenylacetate) oral				*		Hepatic Encephalopathy	Hepato-Renal
MNK-1411 (cosyntropin injection)						DMD <sup>6</sup>	Neurology
EXPRESSGRAFT™ anti-infective (cathelicidin)		*				DFU <sup>7</sup>	Critical Care
NITRIC OXIDE gas for perfusion	*					Transplant Organ Perfusate	Critical Care
EXPRESSGRAFT pro-angiogenic (VEGF <sup>8</sup> )						TBD - Chronic Non-healing Wounds	Critical Care
EXPRESSGRAFT anti-tumor (IL-12 <sup>9</sup> )						TBD - Skin Cancer Recurrence	Critical Care
MP-3964 (TLR9 <sup>10</sup> antagonist)						Transplant Organ Perfusate & AP <sup>11</sup>	Critical Care

Device	Concept	Planning	Development	Qualification	Registration	Details	Diseases/Therapeutic Areas
INOMAX® (Nitric Oxide) gas						Next Generation Device	Critical Care
H.P. ACTHAR® GEL (repository corticotropin injection)						Alternative Delivery Device	Autoimmune
NITRIC OXIDE gas for perfusion						Organ Transplant Device	Critical Care

1 Graft vs Host Disease  
2 Hepatorenal Syndrome  
3 Deep Partial Thickness  
4 Full Thickness

5 Amyotrophic Lateral Sclerosis  
6 Duchenne Muscular Dystrophy  
7 Diabetic Foot Ulcers  
8 Vascular Endothelial Growth Factor

9 Interleukin  
10 Toll-like Receptor  
11 Acute Pancreatitis

\* Anticipated data readout  
in 2019

# Key pipeline products in mid- to late-stages expected to diversify commercial portfolio

Program	Clinical Status	Est. Launch	Est. Exclusivity	Est. Global Peak Net Sales <sup>1</sup>
VTS-270	Phase 3	2020	2027	>\$150mm
Terlipressin	Phase 3	2020	2027	>\$300mm
StrataGraft	Phase 3	2020	2032	>\$150mm
CPP-1X / sulindac	Phase 3	2020	2027	>\$300mm
Xenon gas	Phase 3	2021	2028	>\$300mm
Stanssoporfin	Phase 3	2023	2032	>\$125mm
MNK-6105 (IV) and MNK-6106 (oral)	Phase 2 / Phase 2	2023 / 2024	2029	>\$500mm

**Pipeline expected to drive future growth, contributing greater than 20% of Specialty Brands net sales in 2023**

**Several R&D collaborations in place, including Washington University in St. Louis, to drive early discovery and pipeline development**

<sup>1</sup> Peak net sales estimates are annual, and assume regulatory and commercial success as planned

# Next-generation INOmax EVOLVE™, H.P. Acthar Gel self-injector expected to improve current product offerings

New **INOmax EVOLVE** delivery device designed to improve operational efficiency and advance nitric oxide delivery in the hospital setting.

**INOmax EVOLVE** designed to:

- Reduce human error potential through automation
- Provide improved technological and safety features
- Reduce time between diagnosis and treatment through quick, automated set-up
- Increase number of patients and settings for treatment
- Increase mobility and transportability ease



INOmax EVOLVE creates potential platform in nitric oxide for MNK

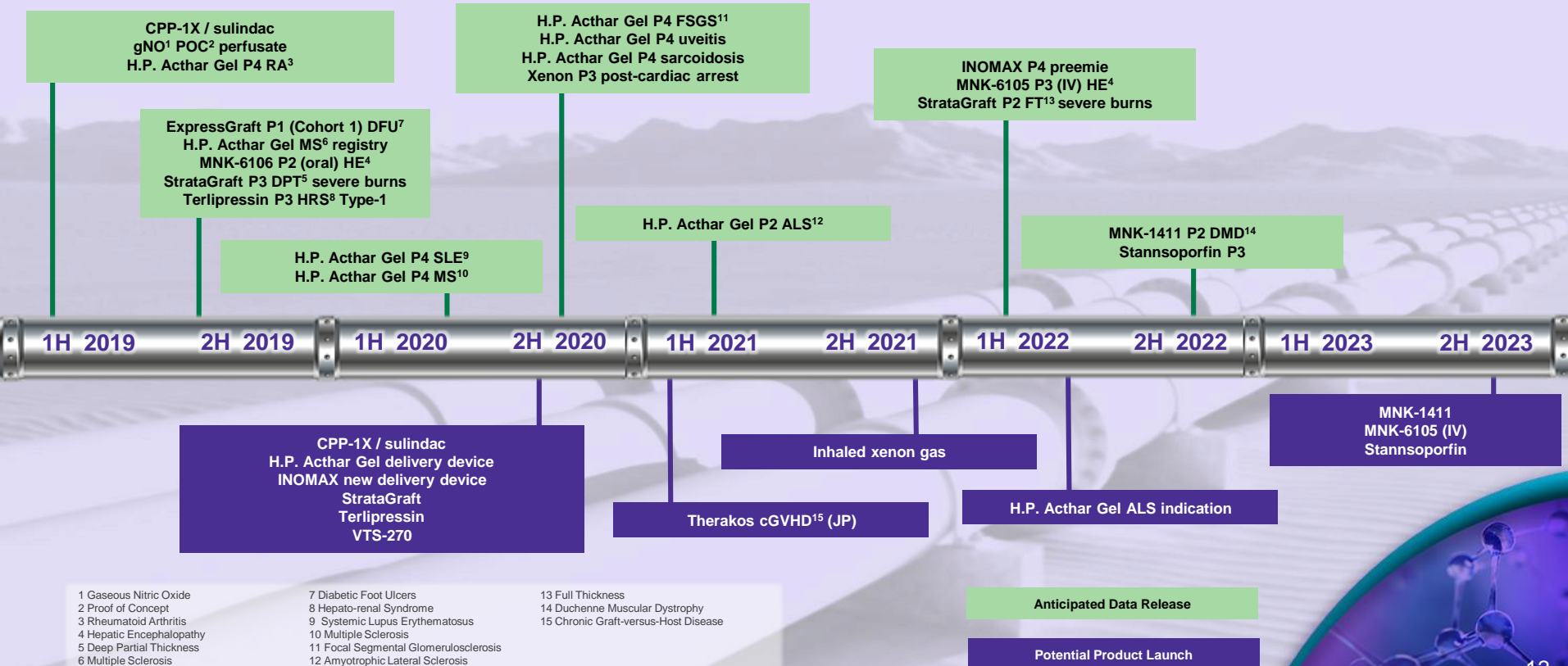
**H.P. Acthar Gel self-injector** designed for improved patient convenience and flexibility.

- **H.P. Acthar Gel self-injector** designed to enhance customer-focused delivery:
  - Easier use for patients with dexterity or vision challenges
  - Single patient-specific dose; no need to draw the product from the current multi-dose vial
- Expected to offer subcutaneous injection system for all currently approved indications except Infantile Spasms
- Provides potential benefit over future competitive ACTH agents, if approved
- Furthers MNK's strategy to generate considerable new data for the product and an improved product presentation



H.P. Acthar Gel self-injector expected to further clinical use and patient experience with the product

# Significant anticipated development catalysts and potential product launches over next five years



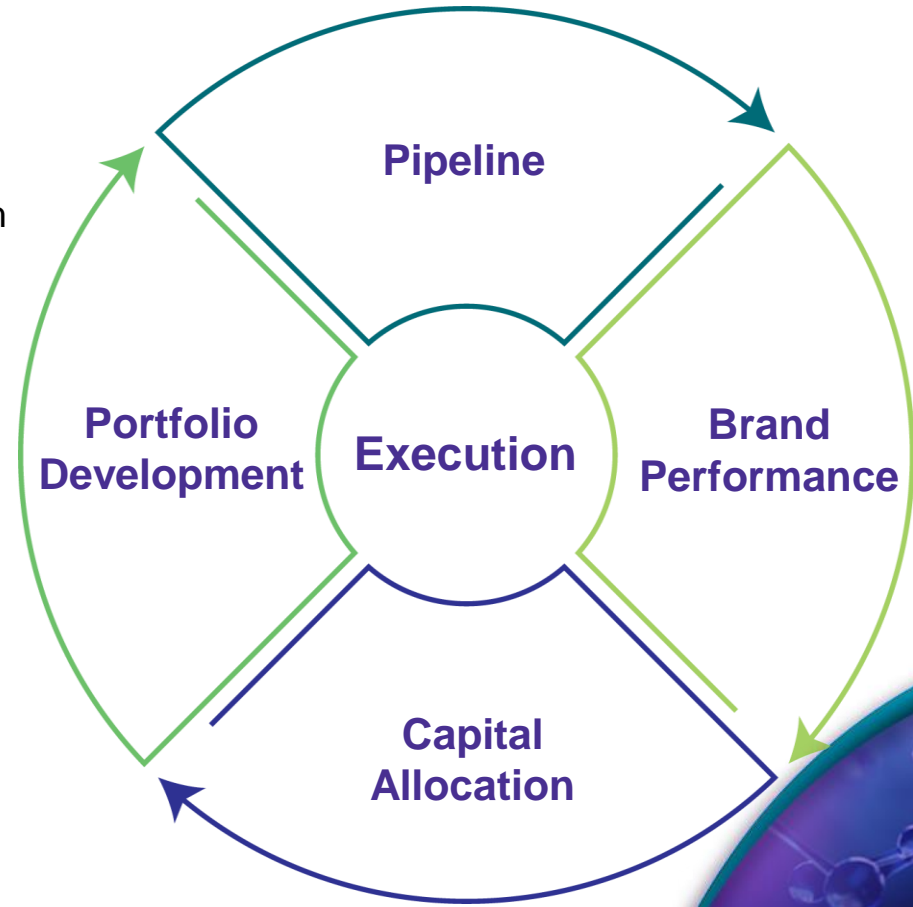
# Focused on increasing stakeholder value via sustainable organic growth

## Strategic vision:

Innovation-driven specialty pharmaceutical growth company focused on improving outcomes for underserved patients with severe and critical conditions

### Strategic Priorities for 2019:

- Maximize value of diversified, inline portfolio
- Advance further data generation and pipeline
- Complete Specialty Generics spin-off
- Execute disciplined capital allocation, with net debt reduction the primary focus



# Thank You